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| 10/530,035 | 08/29/2005 | Bent Karsten Jakobsen | 006090.00018 | 2934 |

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| EXAMINER | |
|---|---|
| SKELDING, ZACHARY S | |
| **ART UNIT** | **PAPER NUMBER** |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/530,035 | JAKOBSEN ET AL. | |
| | Examiner | Art Unit | |
| | Zachary Skelding | 1644 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on 3-9-05 9-23-05.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-37 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-37 are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

1. Applicant's preliminary amendment to the claims, filed March 9, 2005 and Applicant's provision of a sequence listing and computer readable form filed September 23, 2005 are acknowledged.

2. With respect to applicant's amendment to the claims filed March 9, 2005:

   Claims 3-8, 10, 11, 17-24, 26 and 28-36 have been amended.

   Claims 1-37 are pending.

3. With respect to applicant's provision of a sequence listing and computer readable form filed September 23, 2005, it is noted that the instant specification discloses a number of sequences encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2) which are not accompanied by the "SEQ ID NO:" designation as required, see, for example, the instant specification at pages 25-26, Figures 1-3, 5 and in claims 44-45.

   The instant specification must be amended such that all sequences encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2) are accompanied by a identifier "SEQ ID NO:", and a sequence listing including these sequences, computer readable form (CRF) and statement verifying the sequence listing and CRF are the same must be provided. See 37 CFR 1.821-1.825.

   IF, however, the sequence listing provided September 23, 2005 represents a complete listing of all the sequences disclosed in the instant specification required to be identified by SEQ ID NO:, THEN applicant need NOT submit another sequence listing and CRF. However, Applicant must still amend the instant specification to include the SEQ ID NOs:.

   Please note that this includes sequences shown in the Figures (where the SEQ ID NO: identifier can be present either in the drawing and/or in the Brief Description of the Drawings) as well as the claims.

   ***Appropriate correction is required. See MPEP § 2421.***

4. It is further noted that the instant specification contains a description of the drawings but not under the heading "brief description of the drawings" and not in the customary location in the instant specification, i.e., before the "Detailed Description of hte Invention".

   In this regard, the following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use:

**Arrangement of the Specification**

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
(f) BACKGROUND OF THE INVENTION.
(1) Field of the Invention.
(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

***Restriction Requirement***

5. Restriction is required under 35 U.S.C. 121 and 372.

6. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1:

Group I, claim 18, drawn to a scTCR as claimed in claim 1, wherein a cysteine residues has been substituted for Thr 48 of exon 1 of TRAC*01 and Ser 57 of exon 1 of TRBC1*01 or TRBC2*01.

Group II, claim 19, drawn to a scTCR as claimed in claim 1, wherein a cysteine residues has been substituted for Thr 45 of exon 1 of TRAC*01 and Ser 77 of exon 1 of TRBC1*01 or TRBC2*01.

Group III, claim 20, drawn to a scTCR as claimed in claim 1, wherein a cysteine residues has been substituted for Tyr 10 of exon 1 of TRAC*01 and Ser 17 of exon 1 of TRBC1*01 or TRBC2*01.

Group IV, claim 21, drawn to a scTCR as claimed in claim 1, wherein a cysteine residues has been substituted for Thr 45 of exon 1 of TRAC*01 and Asp 59 of exon 1 of TRBC1*01 or TRBC2*01.

Group V, claim 22, drawn to a scTCR as claimed in claim 1, wherein a cysteine residues has been substituted for Ser 15 of exon 1 of TRAC*01 and Glu 15 of exon 1 of TRBC1*01 or TRBC2*01.

Group VI, claim 33, drawn to a method for detecting a TCR ligand.

Group VII, claim 34, drawn to a method of identifying an inhibitor of the interaction between an scTCR and a TCR ligand selected from MHC-peptide complexes, CD 1-antigen complexes, superantigens and MHCpeptide/superantigen complexes comprising contacting the scTCR with a scTCR ligand binding partner, in the presence of and in the absence of a test compound, and determining whether the presence of the test compound reduces binding of the scTCR to the TCR ligand, such reduction being taken as identifying an inhibitor.

Group VIII, claim 35, drawn to a method of identifying a potential inhibitor of the interaction between an scTCR and a TCR ligand selected from MHC-peptide complexes, CD 1-antigen complexes, superantigens and MHC-peptide/superantigen complexes comprising contacting the scTCR or scTCR ligand binding partner with a test compound and determining whether the test compound binds to the scTCR and/or the TCR ligand, such binding being taken as identifying a potential inhibitor.

Group IX, claims 36 and 37, drawn to nucleic acid molecules comprising a sequence encoding a scTCR and a vector comprising said nucleic acid molecule.

Claims 1-17 and 23-32 link the inventions of Groups I-V. The restriction requirement between the linked inventions is **subject to** the nonallowance of the linking claim(s), claim 1-17 and 23-32. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim,

such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

7. The inventions listed as Groups I-IX above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the invention of linking claim 1, for example, was found to have no special technical feature that defined the contribution over the prior art of Weidanz et al. (WO 99/18129, cited on an IDS), see for example, page 53, 1st-2nd paragraph and Figures 9A-B.

   Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and so lack unity of invention.

8. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

***Species Election***

9. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

10. If applicant elects any one of Groups I-V, applicant is required to elect a particular species of linker sequence selected from among the linker sequences recited in claims 15 or 16.

    These species do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features.

    Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

11. If applicant elects any one of Groups I-V, applicant is further required to elect a particular type of variable region and constant region of the scTCR, selected from among the possible combinations recited, for example, in claims 23 and 24, i.e., where the variable region and constant region are "from the same species" or are "from different species".

These species do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

12. Furthermore, if applicant elects any of Groups I-V, applicant is further required to elect a particular molecule to which the claimed TCR binds, for example, "HLA-A2 Tax," as recited on page 28, 1st paragraph of the instant specification OR "a CD-1 antigen complex" OR "a superantigen or peptide-MHC/superantigen complex" as recited in claims 27 and 28, respectively.

    These species do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features.

    Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

13. Furthermore, if applicant elects any of Groups I-V, applicant is further required to elect if the sTCR is monovalent/comprises a singular sTCR OR multivalent/comprises a plurality of sTCRs as recited, for example, in claim 29.

    These species do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features.

    Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

14. If applicant elects any one of Groups VI-VIII, applicant is required to elect particular molecule to which the claimed TCR binds, for example, "HLA-A2 Tax," as recited on page 28, 1st paragraph of the instant specification OR "a CD-1 antigen complex" OR "a superantigen or peptide-MHC/superantigen complex" as recited in claims 33-35.

    These species do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

15. **Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined** even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary Skelding whose telephone number is 571-272-9033. The examiner can normally be reached on Monday - Friday 8:00 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Zachary Skelding, Ph.D.
Patent Examiner
January 4, 2008

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1/3/08